**ORAL ARGUMENT NOT SCHEDULED**

**No.** 19-1120

**IN THE**

# United States Court of Appeals

**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

In re Scottsdale Research Institute, LLC,

*Petitioner*

---

ON PETITION FOR A WRIT OF MANDAMUS TO WILLIAM P. BARR, U.S. ATTORNEY GENERAL, UTTAM DHILLON, ACTING ADMINISTRATOR OF THE U.S. DRUG ENFORCEMENT ADMINISTRATION, AND THE U.S. DRUG ENFORCEMENT ADMINISTRATION

## Petition for a Writ of Mandamus

Matthew C. Zorn
Shane Pennington
YETTER COLEMAN LLP
811 Main Street, Suite 4100
Houston, Texas 77002
(713) 632-8000

*Counsel for Petitioner*
*Scottsdale Research Institute, LLC*

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Page(s)**

## Federal Cases



---

* Authorities upon which we chiefly rely are marked with asterisks.

**Federal Statutes**



**Regulatory Materials**

**Other Authorities**

# GLOSSARY

| | |
|---|---|
| **APA** | Administrative Procedure Act |
| **CSA** | Controlled Substances Act |
| **DEA** | U.S. Drug Enforcement Administration |
| **Decl.** | Declaration of Suzanne Sisley, M.D. |
| **DOJ** | U.S. Department of Justice |
| **Ex.** | Exhibit (Appendix) |
| **FDA** | U.S. Food and Drug Administration |
| **HHS** | U.S. Department of Health and Human Services |
| **MAPS** | Multidisciplinary Association for Psychedelic Studies |
| **NIDA** | National Institute on Drug Abuse |
| **PTSD** | Post-Traumatic Stress Disorder |
| **SRI** | Scottsdale Research Institute, LLC |

## PRELIMINARY STATEMENT

Dr. Sue Sisley did everything by the book. Over the course of a decade, she ran the regulatory gauntlet, earning the blessing of four federal agencies so that she could do groundbreaking clinical research into the efficacy of cannabis to treat veterans suffering from treatment-resistant post-traumatic stress disorder ("PTSD")—some of whom turn to suicide. Through her company, Scottsdale Research Institute, LLC ("SRI"), the Petitioner in this case, she wants to continue that research and investigate other potential applications for cannabis. But poor-quality government cannabis is preventing that from happening.

To comply with federal law, SRI must use federally-sourced cannabis, grown exclusively on a single 12-acre farm run by the University of Mississippi. SRI used this cannabis for its Phase II trials. It arrived in powdered form, tainted with extraneous material like sticks and seeds, and many samples were moldy. Whatever reasons the government may have for sanctioning this cannabis and no other, considerations of quality are not among them. It is not suited for any clinical trials, let alone the ones SRI is doing. Simply put, this cannabis is sub-par.

Thirty months ago, Sisley thought she had a fix. After DEA announced a new policy designed to increase the number of entities permitted to manufacture cannabis for clinical trials and other research endeavors, SRI applied to grow cannabis for its clinical research. Allowing SRI to grow its own cannabis will improve drug quality and give it tighter control over dosages. But the agency has yet to respond. And with new trials around the corner, SRI can wait no longer.

And it shouldn't have to. Before Sisley submitted SRI's application, Congress amended the Controlled Substances Act to address this problem. As part of "Improving Regulatory Transparency for New Medical Therapies Act," it added a requirement that the Attorney General, upon receiving an application to manufacture a Schedule I substance for use only in a clinical trial, publish a notice of application not later than 90 days after accepting the application for filing. 21 U.S.C. § 823(i)(2).

*That date was more than two years ago.*

Thus, agency action has been unlawfully withheld. And in view of an express directive to prioritize applications relating to clinical research, agency action has most certainly been unreasonably delayed.

To determine whether to issue a writ of mandamus to compel agency action, this Court applies the six-part "*TRAC*" test. This case passes the test:

the agency has flouted a non-discretionary deadline to complete a perfunctory—but vitally important—task; significant economic interests and human health and welfare are at stake; it cannot be said that expediting delayed action will interfere with agency activities of a higher or competing priority; and mandamus is warranted regardless of the purity of the motives underlying DEA's unexplained delay.

SRI turns to this Court having exhausted all other avenues of relief. Sisley reached out to the agency no fewer than five times, the media has done a full-court press, and the number of letters from frustrated members of Congress from both parties imploring the agency to act is quickly approaching a dozen. At this juncture, nothing short of a writ from this Court compelling the agency to act will stop the ongoing harm caused by DEA's unlawful and unreasonable delay.

## RELIEF SOUGHT

SRI seeks a writ of mandamus directing the Attorney General, DEA, or its Acting Administrator to issue a "notice of application" by 90 days from the date of service of this petition or fifteen days after the writ issues, whichever is later.

## JURISDICTIONAL STATEMENT

This petition arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 555(b), 702, and 706(1). DEA's failure to issue a notice of SRI's application is agency action both unlawfully withheld and unreasonably delayed.

The Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 et seq., authorizes direct review in this Court of all final determinations, findings, and conclusions of the Attorney General or agency decisions, *id.* § 877. Because agency delay can thwart judicial review, this Court may resolve claims of unreasonable delay "to protect its future jurisdiction." *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984) ("*TRAC*"); *Gottlieb v. Pena*, 41 F.3d 730, 734 (D.C. Cir. 1994). "Were it otherwise, agencies could effectively prevent judicial review of their policy

determinations by simply refusing to take final action." *Cobell v. Norton*, 240 F.3d 1081, 1095 (D.C. Cir. 2001).

Finally, the All Writs Act, 28 U.S.C. § 1651(a), permits this Court to issue writs of mandamus to cure unreasonable delay. *TRAC*, 750 F.2d at 75.

## ISSUE PRESENTED

After DEA announced a new policy designed to increase the number of entities permitted to manufacture cannabis for clinical trials and other research endeavors, SRI applied to manufacture cannabis to support its own FDA-approved clinical trials. Yet thirty months have passed since SRI filed its application, and the agency has done nothing.

Thus, SRI's petition presents two questions:

1. Has the DEA unlawfully withheld or unreasonably delayed agency action under 5 U.S.C. § 706(1)? and
2. Should this Court issue a writ of mandamus under 28 U.S.C. § 1651(a) to compel the agency to issue the statutorily required notice?

## STATEMENT OF THE CASE

The CSA regulates the production, possession, and distribution of controlled substances. *See* 21 U.S.C. §§ 801 et seq. It contains five schedules of drugs, based on their accepted medical uses, their potential for abuse, and their psychological and physical effects on the body, with Schedule I being the most restrictive. *Gonzales v. Raich*, 545 U.S. 1, 13-14 (2005). Schedule I substances cannot be used, except in research. *See id.* at 14.

When Congress enacted the CSA in 1970, it made cannabis a Schedule I drug. *Id.* It did so based, in part, on a recommendation from the Assistant Secretary of the U.S. Department of Health, Education, and Welfare that cannabis be placed in Schedule I "at least until the completion of certain research." *Id.*

Although the CSA provides a mechanism to administratively reschedule cannabis without legislative intervention, *see* 21 U.S.C. § 811, neither DEA nor the Attorney General has ever exercised that prerogative. In fact, DEA repeatedly rejects requests to reschedule. Most recently, in August 2016, it denied a petition from the states of Rhode Island and Washington. *See* Ex. 16 (A157). The agency's rationale for refusing to reschedule is always the same: the dearth of clinical trials demonstrating

cannabis's medical efficacy. *See, e.g.*, *id.* at A154. ("[T]here are no adequate and well controlled studies proving efficacy.").

## I. Through a "closed" regulatory regime, DEA tightly controls clinical research with controlled substances.

### a. Registration framework.

The CSA establishes a "closed" registration system. *Raich*, 545 U.S. at 13. Manufacture and distribution may occur only among registered handlers of controlled substances, referred to as "registrants." *See id.*; 21 C.F.R. § 1300.02(b) (2017). Thus, anyone seeking to manufacture or distribute a controlled substance must apply to DEA. 21 U.S.C. § 822(a)(1). DEA grants a registration if it determines that doing so is consistent with (1) the public interest and (2) U.S. obligations under the Single Convention on Narcotic Drugs, 1961. *Id.* § 823(a).

DEA has promulgated rules and regulations to implement these registration requirements. *See id.* § 821. 21 C.F.R. § 1301.13 (2014), for example, establishes application fees. Section 1301.14(c) explains how DEA processes applications:

> Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned

> to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Administrator shall accept for filing any application upon resubmission by the applicant, whether complete or not.

21 C.F.R. § 1301.14(c) (2010).

DEA's authority over the registration process is not without limits. For example, the agency must register only the number of bulk manufacturers of a Schedule I or II substance necessary to "produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes." 21 U.S.C. § 823(a)(1); 74 Fed. Reg. 2,101, 2,127-2,130 (Jan. 14, 2009) (discussing section 823(a)(1)). From the time it was passed in 1970 until 2015, however, the CSA placed no deadlines on DEA's duty to process applications to manufacture controlled substances.

**b. Delays in processing applications and scheduling.**

Without deadlines, DEA could delay processing applications—even those seeking to facilitate clinical research—for years, with little recourse available to the applicant. These delays can be detrimental to innovation and public health, and they began to cause problems as the CSA moved into the 21st century.

The cases of Belviq and Fycompa are illustrative. *See generally Eisai, Inc. v. FDA*, 134 F. Supp. 3d 384, 387 (D.D.C. 2015) (chronicling the two drugs' stories). The U.S. Food and Drug Administration ("FDA") approved Belviq in June 2012, but the U.S. Department of Health and Human Services ("HHS") recommended the drug for scheduling. With no timetable governing its review, DEA took another year to approve the drug's placement in Schedule IV, delaying its entry into the market. *Id.* at 389. The story with Fycompa, a drug used to treat seizures in patients suffering from epilepsy, is largely the same. *See id.* In fact, the agency's fourteen-month delay led Eisai to seek mandamus from this Court.[1]

Problems with delay were felt all-around, including with controlled substances like cannabis. In one notable instance, an applicant waited more than three years after applying before the agency responded, proposing a denial. *Craker v. DEA*, 714 F.3d 20-21 (1st Cir. 2013). The saga spanned an entire decade, start to finish. *Id.* at 29.

---

[1] Eisai filed a petition in this Court on August 13, 2013. *See In re Eisai Inc.*, No. 13-1243, Doc. No. 1452261 (D.C. Cir.). Eisai argued that DEA's failure to timely schedule Fycompa was unreasonable and asked the Court to intervene. DEA responded that it expected to act by the end of October. *Id.* at Doc. No. 1454740. Then, through an October 17, 2013 notice, it informed the Court that the rule was submitted for publication in the Federal Register. The Court denied the mandamus petition the next week. *Id.* at Doc. 1462438.

### c. Congress adds statutory deadlines to address opaqueness and delay in DEA's processing of a single class of applications: those seeking to manufacture for clinical trials.

In 2015, Congress passed the "Improving Regulatory Transparency for New Medical Therapies Act," H.R. No. 639, Pub. L. No. 114-89, 129 Stat. 703 (2015). Relevant here, the Act added section 823(i)(2), which requires the Attorney General to notice applications to manufacture Schedule I substances for clinical research not later than 90 days after the application is "accepted for filing":

> For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

21 U.S.C. § 823(i)(2).

The purpose of the amendment was clear: to improve transparency and to prioritize applications relating to clinical research. In a section titled "Background and Need for Legislation," the House Report underscores three needs triggering the new "timetable": (1) addressing "[i]nconsistency and lengthy review times at DEA," (2) distinguishing between

"manufacturing of a controlled substance *for marketing* and the manufacturing of a controlled substance *for use in clinical trial*," and (3) putting in place a "*transparent process* for the applicant to determine the reasons for a delay in the application." Ex. 18 at A168-69 (emph. added).

## II. SRI falls within the class of researchers Congress sought to protect from delay.

SRI is an Arizona company dedicated to clinical research. To date, it is the only entity federally approved to do clinical research into the effects of cannabis on veterans with treatment-resistant PTSD. SRI does not encourage or sanction recreational cannabis use, but it does support research to determine the applicability of cannabis as medicine. *See* Decl. at ¶ 2.

The journey of SRI's principal, Dr. Sue Sisley, is well-documented. Over a decade ago, she treated veterans with PTSD in her private practice. Sisley prescribed approved medicines on the market, but discovered that for some, none helped. Many clients disclosed that cannabis worked better. For some, it was the only thing that worked. These experiences inspired her to do clinical research into the safety and efficacy of cannabis with veterans suffering from PTSD. *See* Decl. at ¶¶ 7-11.

Little did she know how difficult it would be. Start to finish, it took her *seven* years to amass the necessary approvals just to *begin* the study.

Unlike other controlled substances, clinical research with cannabis requires obtaining approval from four federal agencies, on top of Institutional Review Board approval. *See* Decl. at ¶¶ 8-19 & n.8 (discussing CNN's Weed 3 documentary); *see also* Ex. 21 (A179) (Rolling Stone article titled "Why Is It So Hard to Study Pot?"). She put together a protocol in 2009, which the FDA approved in 2011. Over the next three years, Sisley secured the approvals of the United States Public Health Service and the National Institute on Drug Abuse ("NIDA") necessary to acquire cannabis for the study. Finally, after other significant setbacks, she finally obtained a Schedule I research license from DEA in April 2016. Only after obtaining these approvals could the research proceed. *See* Decl. at ¶¶ 12-18.

In January 2017, SRI, with the support of the Multidisciplinary Association for Psychedelic Studies ("MAPS"), began its triple-blind clinical study of smoked whole-plant cannabis to treat PTSD symptoms in veterans. A $2.1 million grant to MAPS from the Colorado Department of Public Health and Environment funded the study. Phase II trials[2] finished in February 2019. *See* Decl. at ¶ 19. As we next explain, however, low-quality government cannabis hampered the research.

---

[2] Phase II trials aim to determine if a treatment works, and usually involve 25 to 100 study subjects. Phase III trials compare the safety and effectiveness of a drug against other treatments and involve far more study subjects.

Additional trials with veterans are imminent. SRI also hopes to begin clinical trials to assess the efficacy of cannabis to treat breakthrough pain in cancer patients soon. *See* Decl. at ¶ 26.

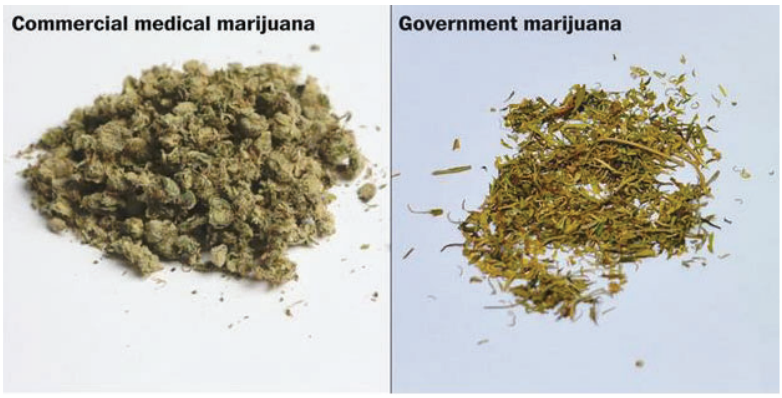
## III. The current supply of federally legal cannabis stifles clinical research.

### a. The NIDA monopoly.

For almost 50 years, the only legal source of cannabis for research in the United States has been a single farm at the University of Mississippi. *See generally Craker*, 714 F.3d at 20 (1st Cir. 2013); Ex. 16 at A158 (81 Fed. Reg. 53,846) ("For nearly 50 years, the United States has relied on a single grower to produce marijuana used in research.").

The quality of the cannabis from this farm—and its delivery logistics—are poor. Some has languished on the shelves for years. It looks more like green talcum powder than medical grade cannabis, Decl. at ¶ 21 & n.11:

Most samples SRI received contained extraneous plant material like sticks and seeds. Ex. 14 at A149-A152 (Lab Report). Others had mold. *See id.* at A146. Also, the government demands researchers indemnify the government to use this study drug, *see* Decl. at ¶22:




SRI complies with federal law, so it had to use this cannabis. Unfortunately, its poor quality undermined results. For example, Sisley observed that sticks and seeds caused bronchial irritation in some subjects. Decl. at ¶ 23. SRI is reticent to indemnify the government, especially because it has told the government it is willing and able to manufacture its own, on-site, high-quality, fresh cannabis under the agency's strict regulations and supervision. *See id.* at ¶ 24. NIDA cannabis is inadequate for a third important reason: Phase III trials require cannabis virtually identical to material used in proposed pharmaceutical medicine. *See id.* at ¶ 25.

Now, SRI looks north of the border for true medical-grade cannabis, because NIDA cannabis falls short. *See id.* at ¶ 26.

**b. To address supply issues, DEA solicits applications to register additional manufacturers of cannabis for clinical research.**

On August 12, 2016, DEA denied a petition from Rhode Island and Washington to reschedule cannabis as a Schedule I substance. Ex. 15 (A153) (81 Fed. Reg. 53,687 (Aug. 12, 2016)). But it also committed to improving the supply of cannabis suitable for clinical research.

DEA explained: "the available evidence is not sufficient to determine that marijuana has an accepted medical use" and that "more research is needed into marijuana's effects, including potential medical uses for marijuana and its derivatives." *Id.* at A155 (81 Fed. Reg. at 53,689). In the letter accompanying the denial, DEA declared "[r]esearch . . . the bedrock of science," DEA committed to "support and promote legitimate research regarding marijuana and its constituent parts." Ex. 22 at A194.

Consistent with that goal, DEA issued a separate notice announcing a new policy to increase the number of entities registered to manufacture cannabis. Ex. 16 (A157) (81 Fed. Reg. 53,846 (Aug. 12, 2016)). DEA declared its "full[] support" of cannabis research and "concluded that the best way to satisfy the current researcher demand for a variety of strains of

marijuana and cannabinoid extracts is to increase the number of federally authorized marijuana growers." *Id*. at A158.

**c. Answering DEA's call, SRI applies to manufacture cannabis for its clinical research.**

Shortly after DEA's August 2016 policy statement, SRI applied to manufacture cannabis to support its clinical research. Ex. 1 (A001) (Oct. 2016 Application); Decl. at ¶ 27. Weeks later, Sisley answered a supplemental questionnaire the agency had remitted. Ex. 2 (A005) (Questionnaire); Decl. at ¶ 28. Asked how cannabis grown by SRI would be used, Sisley stated that the existing supply was not adequate for its clinical trials:

> [SRI] is preparing for phase 3 FDA approved drug development clinical trials with cannabis. Our ultimate goal involves evaluating whether cannabis can be turned into a prescription medicine. The only way to conduct this analysis is through phase 3 trials. However the current supply of research cannabis from cannot be utilized for prescription drug development. It can only be used for academic research. Which is why we are seeking to cultivate a new supply of cannabis to be used for these Phase 3 FDA trials.

Ex. 2 at A011. Sisley also told DEA that SRI could supply other clinical trials in the future. *See id*. at A008, 010, 012.

**d. After soliciting applications, DEA processes none of them.**

The number of applications the agency has processed since August 2016 is zero.

This delay is unusual, unprecedented even. The typical time from application submission to a notice in the Federal Register is months, not years. A 2016 DEA presentation says the process takes *as much* as 4-6 months to complete. Ex. 3 at A083 (DEA Presentation). DEA routinely processes applications within this timeframe:

- On December 12, 2018, Siemens Healthcare Diagnostics Inc. applied to be a bulk manufacturer of Ecgonine, a Schedule II substance. A notice in the Federal Register followed on March 21, 2019. 84 Fed. Reg. 10,534.
- On October 12, 2018, Johnson Matthey Inc. applied to be a bulk manufacturer of Schedule I and II substances. A notice in the Federal Register followed on February 21, 2019. 84 Fed. Reg. 5,477.
- On August 22, 2018, Insys Manufacturing, LLC applied to be a bulk manufacturer for Marijuana and Tetrahydrocannabinols to produce synthetic ingredients for product development and distribution to customers. A notice in the Federal Register followed on March 21, 2019. 83 Fed. Reg. 54,611.

The agency approved eight applications in September 2017, *see* 82 Fed. Reg. 44,842 (Sept. 26, 2017), and seven more in May 2018, *see* 83 Fed. Reg. 22,518 (May 15, 2018). In short, these applications do not take years to process.

**e. Substantial efforts to obtain agency action without Court intervention have failed.**

Sisley has repeatedly reached out to DEA to check the status of SRI's application. *See, e.g.*, Ex. 13 (A139) (Aug. 30, 2018 e-mail); *see also* Decl ¶¶ 30-31. Every time, the message is the same: no progress.

This unusual delay has sparked media attention. *See, e.g.*, Ex. 19 (A170) (Wall St. Journal article titled "Marijuana-Research Applications Go Nowhere at Justice Department"); Ex. 20 (A174) (Washington Post article titled "Justice Department at Odds with DEA on Marijuana Research, MS-13 Washington Post" explaining how government officials were just "sitting on" the applications and that DOJ "effectively shut down" the program). Members of Congress from both sides of the aisle have repeatedly asked the Attorney General and DEA for status updates:

- **April 12, 2018:** former Senator Hatch and Senator Harris ask for an update on applications to manufacture cannabis for research and a commitment to resolve outstanding applications by August 11, 2018. Ex. 5 (A107).
- **July 25, 2018:** a bipartisan group of eight senators inquire about the status of the applications and request answers by August 10. Ex. 9 (A124).
- **August 30, 2018:** a bipartisan group of congressmen write to the Secretary of Veterans Administration about the need to conduct "a rigorous clinical trial into the safety and efficacy of medicinal cannabis for veterans with post-traumatic stress disorder (PTSD) and

chronic pain so that we can better understand the potential benefits or dangers of medicinal cannabis." Ex. 6 (A112).

- **August 31, 2018:** another bipartisan group of congressmen urge DEA to end the delay. Ex. 7 (A115).
- **September 28, 2018:** another bipartisan group of fifteen congressmen express concern over DEA's delay. Ex. 8 (A119).
- **March 28, 2019:** Senators Schatz and Booker urge the Attorney General to move forward. Ex. 10 (A128).
- **April 2, 2019:** another bipartisan group of six senators question DEA's efforts to process applications. Ex. 11 (A131).
- **May 7, 2019:** another bipartisan group of *thirty* congressmen urge the agency to do more "because the matter is of such importance." Ex. 12 (A135).

To SRI's knowledge, neither the Attorney General nor DEA has responded to *any* of these inquiries. In fact, as of December 28, 2018, DEA reported that it "continues to review applications for registration . . . ." 83 Fed. Reg. 67,348, 67,350 (Dec. 28, 2018). Thus, well past the two-and-a-half-year mark, SRI's application continues to languish in agency purgatory.

## SUMMARY OF THE ARGUMENT

DEA's delay in noticing or responding to SRI's application is unlawful, unreasonable, and egregious. It contravenes the letter and spirit of the CSA, seriously harms SRI, and hampers SRI's efforts to help suffering veterans through clinical research. Everyone—including the agency—agrees that this research is important and that the need for research generally is urgent. Here, DEA can act with little expenditure of resources.

The Court should issue the extraordinary writ of mandamus because DEA's inexplicable delay is the only remaining impediment to research of urgent importance to the health and welfare of millions of Americans.

## STANDING

When a claim is based on an alleged deprivation of a procedural right, such as the right to have an agency process an application consistent with congressional command, "the primary focus of the standing inquiry is not the imminence or redressability of the injury to the [petitioner]" but instead whether "the government act performed without the procedure in question will cause a distinct risk to a particularized interest of the plaintiff." *City of Dania Beach v. FAA*, 485 F.3d 1181, 1185 (D.C. Cir. 2007) (cites omitted). A petitioner in such a case "never has to prove that if he had received the

procedure the substantive result would have been altered." *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 94 (D.C. Cir. 2002). Instead, "[a]ll that is necessary is to show that the procedural step was connected to the substantive result." *Id.* at 94-95.

Petitioner has standing because it is suffering an injury directly traceable to DEA's delay in processing its application that can be redressed by the relief requested. *See generally Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Petitioner submitted its application to manufacture cannabis for use in clinical trials and paid DEA thousands of dollars. *See* Ex. 4 at A106 (showing application fee). Under the plain language of both section 823(i)(2) and the APA, Petitioner was entitled to have DEA issue a notice regarding its application in the Federal Register to commence the process for determining whether Petitioner should be registered under the Act. 81 Fed. Reg. at 53,848. Petitioner and its patients have suffered other harms as well from the agency's inaction, including being saddled with cannabis ill-suited for clinical research.

## ARGUMENT: REASONS WHY THE WRIT SHOULD ISSUE

### I. Legal Standard

To show entitlement to mandamus, SRI must demonstrate: "(1) a clear and indisputable right to relief, (2) the government agency or official

is violating a clear duty to act, and (3) that no adequate alternative remedy exists." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (citing *United States v. Monzel*, 641 F.3d 528, 534 (D.C. Cir. 2011)). These requirements are jurisdictional; unless all are met, the Court must dismiss. *Id.* (cites omitted). "Even when the legal requirements for mandamus jurisdiction have been satisfied, however, a court may grant relief only when it finds compelling equitable grounds." *Id.* (quoting *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005)). SRI must therefore show that its "right to issuance of the writ is clear and indisputable." *Id.* (quoting *Power v. Barnhart*, 292 F.3d 781, 784 (D.C. Cir. 2002)).

Mandamus claims like SRI's that "target agency delay[] turn on 'whether the agency's delay is so egregious as to warrant mandamus.'" *Id.* (quoting *In re Core Commc'ns, Inc.*, 531 F.3d 849, 855 (D.C. Cir. 2008)). In making that assessment, this Court looks to the so-called "*TRAC* factors"

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not

> "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.'"

*TRAC*, 750 F.2d at 80 (cites omitted).

"[W]here the statute imposes a deadline or other clear duty to act, the bulk of the *TRAC* factor analysis may go to the equitable question of whether mandamus *should* issue, rather than the jurisdictional question of whether it *could*." *Am. Hosp. Ass'n*, 812 F.3d at 189-90. That is the case here. Accordingly, SRI folds its discussion of the first two jurisdictional requirements into its analysis of the *TRAC* factors and addresses the only remaining jurisdictional issue—whether an adequate alternative remedy exists—separately.

## II. DEA's egregious delay warrants mandamus.

DEA's "recalcitrance . . . in the face of a clear statutory duty" calls out for mandamus. *Pub. Citizen Health Research Grp. v. FDA*, 740 F.2d 21, 32 (D.C. Cir. 1984) (citing 5 U.S.C. §§ 555(b), 706(1)). The first five *TRAC* factors strongly favor the exercise of equitable discretion, and the sixth—improper conduct or motive—is not a prerequisite for mandamus. *TRAC*, 750 F.2d at 80. The APA commands DEA "to conclude a matter presented to it within a reasonable time," 5 U.S.C. § 555(b), and courts must "compel

agency action unlawfully withheld or unreasonably delayed," *id.* § 706(1). If those imperatives apply anywhere, they apply here.

**a. Congress's mandate that DEA "issue a notice of application not later than 90 days after the application is accepted for filing" supplies the applicable rule of reason.**

Of the six *TRAC* factors, "[t]he first and most important . . . is that 'the time agencies take to make decisions must be governed by a "rule of reason."'" *In re Core Comm'cns, Inc.*, 531 F.3d at 855 (quoting *TRAC*, 750 F.2d at 80). Even absent an express statutory deadline, this factor can weigh in favor of mandamus. But as the second *TRAC* factor clarifies, the analysis is simpler where "Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed." *TRAC*, 750 F.2d at 80. When Congress commands an agency to complete a discrete, ministerial duty within a defined timeframe, the "statutory scheme suppl[ies] content for this rule of reason . . . ." *Id.*

That is the case here. Section 823(i)(2)'s command that DEA "shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing," imposes a non-discretionary duty on DEA to take a discrete, ministerial action. 21 U.S.C. § 823(i)(2). The statute conveys both a clear duty (on DEA) and an equally clear right (on SRI). Once SRI's application

was accepted for filing, DEA had a duty to "issue a notice of [SRI's] application," and SRI's indisputable right to receive that notice within "90 days" arose automatically. *See* Ex. 16 at A160 (recognizing applicants' "due process" interest in having DEA process application to manufacture).[3]

In cases like this one, where Congress has given the agency a *specific* task to complete within a *relatively brief* timeframe, this Court has described "Congress's intent that that agency act promptly" as "manifest[ ]." *In re People's Mojahedin Org. of Iran*, 680 F.3d 832, 837 (D.C. Cir. 2012); *compare, e.g.*, *Baptist Mem. Hosp. v. Sebelius*, 603 F.3d 57, 63 (D.C. Cir. 2010) (denying mandamus relief because there is no clear duty to act where the statutory language—"may"—is permissive and not mandatory). Although there "is 'no *per se* rule as to how long is too long' to wait for agency action," this Court has held that "a reasonable time for agency action is typically counted in weeks or months, not years." *In re Am. Rivers and Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004) (quoting *In re Int'l Chem. Workers Union*, 958 F.2d 1144, 1149 (D.C. Cir. 1992) (per curiam)); *see also, e.g.*, *MCI Telecomms. Corp. v. FCC*, 627

[3] Of course, the agency also has a duty not to unreasonably delay agency action under the APA. *See* 5 U.S.C. §§ 555(b), 706(1). The 90-day deadline confirms that Congress intended for reasonable delay in this area to be months, not years.

F.2d 322, 327 (D.C. Cir. 1980) (over three years); *Midwest Gas Users Ass'n v. FERC*, 833 F.2d 341, 359 (D.C. Cir. 1987) (four years).

In *People's Mojahedin*, for example, this Court held that a twenty-month failure to act on a 180-day statutory deadline "plainly frustrates the congressional intent and cuts strongly in favor of granting [the] mandamus petition." 680 F.3d at 837. DEA's inaction in this case is far more egregious: in the face of a purely ministerial act due in half the time, the agency has unlawfully withheld the required action for almost twice as long. If an agency's refusal to act that exceeds the statutory timeframe by 333% "cuts strongly in favor of granting [the] mandamus petition," as this Court held in *People's Mojahedin*, 680 F.3d at 837, then it is hard to see how unexplained delay outstripping the congressionally-imposed timeframe by a staggering 1200% (and counting) is not also egregious.

DEA's delay also indisputably "frustrates congressional intent." *Id.* Congress imposed the 90-deadline in section 823(i)(2) as a direct response to DEA's delays with respect to applications like SRI's. *See* Ex. 18 at A168-69 (explaining that purpose of amendment was to remedy "[i]nconsistency and *lengthy* review times at DEA" and to establish a "*transparent process* for the applicant to determine the reasons for a delay in the application.") (emph. added). DEA's flat disregard of that mandate doesn't just *frustrate*

Congress's purpose; it eviscerates it. This strongly favors mandamus. *See Cutler v. Hayes*, 818 F.2d 879, 897-98 (D.C. Cir. 1987) ("The court must also estimate the extent to which delay may be undermining the statutory scheme.").

Several other considerations confirm the unreasonableness of the delay. First, DEA interprets similar statutory deadlines under the CSA as requiring agency action by a date certain. Consider, for example, section 811(j), another 90-day deadline Congress added to the CSA with the 2015 Improving Regulatory Transparency for New Medical Therapies Act. 21 U.S.C. § 811(j). In language that mirrors section 823(i)(2)'s mandate, section 811(j) provides that when DEA receives notification from HHS that it has indexed a drug under section 572 of the Food Drug and Cosmetic Act, 21 U.S.C. § 360, "the Attorney General shall, not later than 90 days after the date described in paragraph (2), issue an interim final rule . . . ." 21 U.S.C. 811(j)(1).

Less than a year after both sections 811(j)(1) and 823(i)(2) were added to the CSA, DEA had already issued an interim final rule within the 90-deadline. In that interim rule, DEA noted the deadlines Congress had imposed in the 2015 amendment and interpreted the 90-day deadline in

section 811(j)(1) as requiring it to act on HHS's recommendation "not later than 90 days" after the date described in section 811(j)(2):

> Under the Controlled Substances Act (CSA), as amended in 2015 by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114-89), where the DEA receives notification from HHS that the Secretary has indexed a drug under section 572 of the FDCA, *the DEA is required to issue an interim final rule controlling the drug not later than 90 days after receiving such notification from HHS*. 21 U.S.C. 811(j).

81 Fed. Reg. 58,834, 58,835 (Aug. 26, 2016) (emph. added).

Where Congress uses similar words in different provisions of a similar statute, courts presume that it intended them to carry the same meaning. *IBP, Inc. v. Alvarez*, 546 U.S. 21, 34 (2005) ("[I]dentical words used in different parts of the same statute are generally presumed to have the same meaning."); *see also Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1,11 (D.C. Cir. 2011) (same).

The agency's disparate treatment of these twin deadlines is not reasonable. Indeed, though Congress gave DEA 90 days to complete the tasks required under sections 811(j)(1) and 823(i)(2), the agency's duty under the former requires substantially more resources from DEA than its duty under the latter. Unlike section 823(i)(2), which merely requires DEA to publish a two-page notice in the Federal Register, section 811(j)(1) requires the agency to "issue an interim final rule" controlling a drug. The

August 26, 2016 interim final rule discussed above fills a full 15 pages of the Federal Register. DEA's ability to complete these complex administrative tasks in 90 days underscores the egregiousness of its failure to take simple action here.

Second, other CSA provisions give DEA *less* time to do *more*. Section 823(i)(1), for example, gives DEA just 180 days to process, review, and decide whether to grant or issue an order show cause as to applications to manufacture other controlled substances for use in clinical trials. 21 U.S.C. § 823(i)(1). If six months is a reasonable amount of time for DEA to process, review, and issue an initial decision with respect to similar applications, then it is more than enough time to do far less: notice SRI's application. Other examples abound.[4]

Third, DEA routinely notices applications to manufacture controlled substances, including cannabis, months after filing. *See* examples listed

[4] *E.g.*, 21 U.S.C. § 826(h)(1) (within 30 days of receipt of request to increase quotas applicable to controlled substance, agency must (1) "complete review of such request" and (2) either increase the quota as requested or else provide a written explanation "detailing the basis for [its] determination" "that the level requested is not necessary to address a shortage of a controlled substance"); 21 U.S.C. § 826a (12 months to prepare and submit to House Committee on Energy and Commerce and Committee on the Judiciary of the Senate "a report on drug shortages"); *id.* § 827(f)(1)-(3)(A) (demanding quarterly publication of data on the number of distributors of controlled substances); *id.* § 823(h)(2) (one year after consulting with the Secretary of HHS to "promulgate final regulations specifying . . . (A) the limited circumstances in which a special registration . . . may be issued; and (B) the procedure of obtaining a special registration").

*supra* p. 17. And in a presentation DEA's Office of Diversion Control made in mid-April 2016—right around the time that it received SRI's application—the agency described its process for noticing applications in detail before warning that it *sometimes* "takes 4-6 *months* to complete." Ex. 3 at A083 (2016 DEA Presentation) (emph. added). Whether measured by the agency's past practice or its public statements, the delay at issue here is beyond the pale.

Fourth, DEA's extensive delays persist years after (1) Congress amended the statute to demand the very action DEA continues to withhold, (2) DEA told the public it desired applications like SRI's, *see* Ex. 16 (A158), and (3) DEA publicly acknowledged SRI's due process right to consideration of its application, *id.* at A160 ("Any person who applies for a registration to grow marijuana . . . is entitled to due process in the consideration of the application by the Agency."). There is no excuse for DEA's refusal to act in this case. Nor is there any reason to believe it will act absent judicial intervention. Accordingly, the Court should not hesitate to exercise its equitable discretion.

**b. DEA's unreasonable delay has caused and continues to cause extreme prejudice and concrete harm to health and human welfare.**

The third and fifth *TRAC* factors, which assess the impact of the delay, strongly favor mandamus. 750 F.2d at 80. Under the third *TRAC* factor, courts recognize that delays that relate to health and welfare are more likely to necessitate judicial intervention than those that simply may have economic consequences. *Id.* Under the fifth *TRAC* factor, courts consider the nature and extent of the interests prejudiced by the agency's delay. *Id.* These factors are appropriately addressed together because the prejudice SRI suffers is co-extensive with the harm courts have found particularly suited for mandamus relief: harm to human health and welfare.

It was concern for human health and welfare that prompted Congress to add statutory deadlines to the CSA provisions requiring DEA to process applications to manufacture controlled substances for use in clinical trials. The Committee Report on H.R. 639—the bill that would eventually become the "Improving Regulatory Transparency for New Medical Therapies Act"—explains that the deadlines were necessary "to facilitate patient access to new therapies in an efficient and transparent manner . . . ." Ex. 18 at A168-69; *see also* Ex. 19 at A164 (representative Pitts stating that deadlines were meant to "improve the transparency and consistency of the [DEA]'s . . .

registration process for the manufacture of controlled substances for use in clinical trials" because doing so would "allow new and innovative treatments to get to patients who desperately need them"); *id.* ("This legislation was introduced . . . to provide a solution to delays experienced by patients in need."); *id.* ("Further, section 3 of this bill would bring much-needed certainty to another open-ended DEA process . . . manufacturers of controlled substances intended to be used in clinical trials for products not yet approved by the FDA."). Representative Pitts, Chairman of the House Subcommittee on Health of the Committee on Energy and Commerce explained:

> This bill also establishes a timeline for DEA to grant approval of manufacturers' applications to register controlled substances not yet approved by FDA to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies. *This provision will get products to the market faster because innovators will be able to get clinical trials under way in a timely and predictable way, which is critical to drug developers and patients alike.*

Ex. 23 at A199 (hearing remarks) (emph. added).

DEA's ongoing delays on an issue so vital to public health have frustrated just about everyone. As one bipartisan group of Senators put it in their July 25, 2018 letter to then Attorney General Jeff Sessions: "Our nation's need for meaningful federally sanctioned research is critical"

because "[r]esearch and medical communities should have access to research-grade materials to answer questions around marijuana's efficacy and potential impacts, both positive and adverse." Ex. 9 at A125. And just a week ago, a Second Circuit panel reviewing the propriety of classifying cannabis as a Schedule I substance emphasized that, in light of the "unusual health related circumstances" implicated by DEA's approach to cannabis regulation, "what has counted as appropriate speed in the past may not count as appropriate speed" anymore. *Washington v. Barr,* No. 18-859-CV, 2019 WL 2292194, at *8 (2d Cir. May 30, 2019).

Millions of Americans believe cannabis holds the key to ending their pain and suffering, making the need for clinical trials acute no matter the outcome of SRI's clinical trials. If those studies show that thirty-eight states (and counting), doctors, legislators, and the American public are all wrong—i.e., that cannabis lacks medical utility—then we must know this now. Those using cannabis to treat conditions like PTSD may be jeopardizing their health and welfare. But in the more likely alternative—i.e., SRI's studies prove that cannabis has medical value—DEA's delay inexcusably deprives combat veterans and others of a treatment option necessary to ease their pain. Either way, more delay is unconscionable.

Simply put, the ongoing harm to human health from DEA's delay in this case is *certain*. As a result, any deference owed the agency is "sharply reduced." *See Cutler*, 818 F.2d at 898 ("The deference traditionally accorded an agency to develop its own schedule is sharply reduced when injury likely will result from avoidable delay.").

DEA's delay is also a disincentive to investors. As DEA has acknowledged, "[f]unding may actually be the most important factor in whether research with marijuana (or any other experimental drug) takes place." Ex. 16 at A158, n.2. But when DEA won't even process applications to obtain the materials to *begin* research, investors are less likely to support the research to completion. Where economic considerations implicate human health and welfare, this Court has favored compelling agency action. *See TRAC*, 750 F.2d at 86 (finding that the third *TRAC* factor weighed in favor of compelling agency action because of impact on health and human welfare where the agency had delayed adjudicating claims for a form of unemployment assistance payments).

Zooming out brings other important concerns into focus. For example, it is no secret that, despite federal prohibition, medicinal cannabis is a growing billion-dollar industry at the state level; it might be the largest industry focused solely on transacting contraband since Prohibition. And

with that comes profound economic consequences. The conflict between state and federal law is reason enough to compel the agency to act. DEA says the main obstacle preventing it from recognizing medicinal cannabis at the federal level is the lack clinical research. SRI is trying to solve that problem. But the agency won't act, making the problem worse, not better.

Were it just human health and welfare at stake, the case for mandamus would be quite compelling. But the convergence of health interests and important national interests behind SRI's application should remove any hesitation this Court may have.

**c. No competing priority justifies DEA's delay.**

DEA's unlawful delay has not been, and cannot be, justified by any need to attend to competing priorities. *TRAC*, 750 F.2d at 80. Because Congress expressly amended the CSA to add deadlines for clinical-research-based manufacture applications, it necessarily concluded that these applications must be an agency priority. *See People's Mojahedin*, 680 F.3d at 837 (where command is specific and deadline to act imposed is relatively brief, Congress's intent that the agency act with dispatch is "manifest[]").

Moreover, just three months ago, the President issued an Executive Order on a National Roadmap to Empower Veterans and End Suicide declaring "we must do better in fulfilling our solemn obligation to care for

all those who have served our country," that it "*is the policy of the United States* to end veteran suicide through the development of a comprehensive plan to empower veterans and end suicide through coordinated suicide prevention efforts, *prioritized research activities*, and strengthened collaboration across the public and private sectors," that "[a]nswering this call to action requires an aspirational, innovative, all-hands-on-deck approach to public health — *not government as usual*." Exec. Order No. 13,861, 84 Fed. Reg. 8,585 (Mar. 5, 2019) (emph. added). Noticing SRI's application would be a great start.

Where an agency offers no "'plea of administrative error, administrative convenience, practical difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources,'" this factor favors mandamus. *In re Am. Rivers*, 372 F.3d at 420 (quoting *Cutler*, 818 F.2d at 898). DEA has never offered such a plea, and for good reason. It cannot seriously argue drafting and publishing a two-page notice in the Federal Register would deplete agency resources. This is the epitome of perfunctory.

Accordingly, this *TRAC* factor also underscores the urgency of mandamus relief.[5]

**d. Agency impropriety is not a prerequisite for mandamus.**

SRI does not concede the purity of DEA's motives,[6] but ultimately, the agency's intent is of little concern. The manifest egregiousness of its ongoing delay justifies mandamus even without ill intent. *See TRAC*, 750 F.2d at 80.

## III. SRI has no adequate alternative remedy.

Mandamus is SRI's only path to relief. The "no adequate remedy" requirement is "'a condition designed to ensure that the writ will not be used as a substitute for the regular appeals process.'" *United States v. Jicarilla Apache Nation*, 564 U.S. 162, 206 n.11 (2011) (Ginsburg, J., concurring) (quoting *Cheney v. United States Dist. Ct. for D.C.*, 542 U.S.

---

[5] In a series of unreasonable-agency-delay cases, this Court has held that mandamus claims cannot be used "to jump the line, functionally solving [a petitioner's] delay problem at the expense of other similarly situated applicants." *Am. Hosp. Ass'n*, 812 F.3d at 192 (discussing *In re Barr Labs., Inc.*, 930 F.2d 72 (D.C. Cir. 1991), and *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094 (D.C. Cir. 2003)). Those cases do not control here for a variety of reasons, most notably that SRI does not seek to "get ahead" of any other applicant seeking registration to manufacture for clinical trials.

[6] *See* Ex. 19 (A170) (Washington Post article quoting DEA official who said that DOJ "effectively shut down [the] program to increase research registrations"); *cf. Washington*, 2019 WL 2292194, at *7 (May 30, 2019) ("Plaintiffs document that the average delay in deciding petitions to reclassify drugs under the CSA is approximately nine years.").

367, 380-81 (2004)). Mandamus is appropriate, however, when an agency's unreasonable delay threatens to thwart judicial review, making issuance of the writ necessary "to protect its future jurisdiction." *TRAC*, 750 F.2d at 76; *Gottlieb v. Pena*, 41 F.3d 730, 734 (D.C. Cir. 1994) ("[T]he proper recourse for a party aggrieved by delay that violates a statutory deadline is to apply for a court order compelling agency action.") (cites omitted).

Here, DEA's refusal to take even the simplest administrative step cuts off all other avenues of judicial review, thrusting SRI's application into administrative purgatory.

## CONCLUSION

Petitioner SRI respectfully requests this Court issue a writ of mandamus compelling the Attorney General, DEA, or its Acting Administrator to issue a "notice of application" by 90 days from the date of service of this petition or fifteen days after the writ issues, whichever is later. Notably, mandamus here will not divest the agency of its discretion. It simply allows the process contemplated by the statute to begin, not end. The agency still maintains discretion to deny or delay the application, *see, e.g.*, 21 U.S.C. § 823(i)(2) (". . . the Attorney General shall register the

applicant, *or serve an order to show cause* upon the applicant in accordance with section 824(c) . . .”), should that continue to be its choice.

Dated June 6, 2019

Respectfully Submitted,

Matthew C. Zorn (admission pending)
Shane Pennington
YETTER COLEMAN LLP
811 Main Street, Suite 4100
Houston, Texas 77002
(713) 632-8000
mzorn@yettercoleman.com
spennington@yettercoleman.com

*Counsel for Petitioner*
*Scottsdale Research Institute, LLC*

## CERTIFICATE OF COMPLIANCE

This Petition complies with the Federal Rule of Appellate Procedure 21(d) because it contains 7,649 words, excluding the accompanying documents required by Rule 21(a)(2)(C).

I further certify that this Petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the Petition has been prepared in Georgia 14-point font using Microsoft Word.

*/s/ Shane Pennington*

Shane Pennington
YETTER COLEMAN LLP
811 Main St. Suite 4100
Houston, TX 77002
(713) 632-8000

*Counsel for Petitioner*
*Scottsdale Research Institute, LLC*

## CERTIFICATE OF SERVICE

I certify that on June 6, 2019, I caused this petition, including all exhibits and addenda, to be served by U.S. postal mail on Respondents, as follows:

William P. Barr, Attorney General
United States Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530

Uttam Dhillon, Acting Administrator
United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

*/s/ Shane Pennington*
Shane Pennington

# ADDENDA

## Certificate as to Parties, Rulings, and Related Cases

Pursuant to D.C. Circuit Rules 21(d) and 28(a)(1), counsel for Petitioner states as follows:

### A. Parties and Amici

SRI and Respondents William P. Barr, Uttam Dhillon, and DEA are the only parties to this matter. SRI is not aware of any amici who may appear.

### B. Rulings Under Review

This is a petition for a writ of mandamus to redress agency action unlawfully withheld and unreasonable delayed by DEA in noticing Petitioner's application. Accordingly, there is no agency or judicial decision under review.

### C. Related Cases

Although there are no related cases that have been litigated in the district court, in this Court, or elsewhere, SRI may file a petition for review in this Court concurrent with this petition in a separate action soon after.

/s/ *Shane Pennington*
Shane Pennington

Dated: June 6, 2019

## Corporate Disclosure Statement

In accordance with Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, Petitioner provides the following:

Scottsdale Research Institute, LLC states that it is an Arizona-based limited liability company under Arizona law. It is dedicated to advancing the state of medical care through rigorous research. Specifically, Petitioner aims to conduct high quality, controlled scientific studies intended to ascertain the general medical safety and efficacy of cannabis and cannabis products and examine various forms of cannabis administration. Petitioner has no parent corporation and no publicly held company owns a 10 percent or greater interest of its stock.

/s/ *Shane Pennington*
Shane Pennington

Dated: June 6, 2019

# Statutory Addendum

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated
Title 21. Food and Drugs (Refs & Annos)
Chapter 13. Drug Abuse Prevention and Control (Refs & Annos)
Subchapter I. Control and Enforcement
Part C. Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

21 U.S.C.A. § 823

# § 823. Registration requirements

Effective: October 24, 2018
Currentness

**(a) Manufacturers of controlled substances in schedule I or II**

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

**(1)** maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;

**(2)** compliance with applicable State and local law;

**(3)** promotion of technical advances in the art of manufacturing these substances and the development of new substances;

**(4)** prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

**(5)** past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and

**(6)** such other factors as may be relevant to and consistent with the public health and safety.

**(b) Distributors of controlled substances in schedule I or II**

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

**(1)** maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

**(2)** compliance with applicable State and local law;

**(3)** prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

**(4)** past experience in the distribution of controlled substances; and

**(5)** such other factors as may be relevant to and consistent with the public health and safety.

**(c) Limits of authorized activities**

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

**(d) Manufacturers of controlled substances in schedule III, IV, or V**

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

**(1)** maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;

**(2)** compliance with applicable State and local law;

**(3)** promotion of technical advances in the art of manufacturing these substances and the development of new substances;

**(4)** prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

**(5)** past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and

**(6)** such other factors as may be relevant to and consistent with the public health and safety.

**(e) Distributors of controlled substances in schedule III, IV, or V**

The Attorney General shall register an applicant to distribute controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

**(1)** maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;

**(2)** compliance with applicable State and local law;

**(3)** prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

**(4)** past experience in the distribution of controlled substances; and

**(5)** such other factors as may be relevant to and consistent with the public health and safety.

**(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances**

The Attorney General shall register practitioners (including pharmacies, as distinguished from pharmacists) to dispense, or conduct research with, controlled substances in schedule II, III, IV, or V and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet, if the applicant is authorized to dispense, or conduct research with respect to, controlled substances under the laws of the State in which he practices. The Attorney General may deny an application for such registration or such modification of registration if the Attorney General determines that the issuance of such registration or modification would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

**(1)** The recommendation of the appropriate State licensing board or professional disciplinary authority.

**(2)** The applicant's experience in dispensing, or conducting research with respect to controlled substances.

**(3)** The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

**(4)** Compliance with applicable State, Federal, or local laws relating to controlled substances.

**(5)** Such other conduct which may threaten the public health and safety.

Separate registration under this part for practitioners engaging in research with controlled substances in schedule II, III, IV, or V, who are already registered under this part in another capacity, shall not be required. Registration applications by practitioners wishing to conduct research with controlled substances in schedule I shall be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol. The Secretary, in determining the merits of each research protocol, shall consult with the Attorney General as to effective procedures to adequately safeguard against diversion of such controlled substances from legitimate medical or scientific use. Registration for the purpose of bona fide research with controlled substances in schedule I by a practitioner deemed qualified by the Secretary may be denied by the Attorney General only on a ground specified in section 824(a) of this title. Article 7 of the Convention on Psychotropic Substances shall not be construed to prohibit, or impose additional restrictions upon, research involving drugs or other substances scheduled under the convention which is conducted in conformity with this subsection and other applicable provisions of this subchapter.

**(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver**

**(1)** Except as provided in paragraph (2), practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain annually a separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment (or both)

**(A)** if the applicant is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought;

**(B)** if the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting (i) security of stocks of narcotic drugs for such treatment, and (ii) the maintenance of records (in accordance with section 827 of this title) on such drugs; and

**(C)** if the Secretary determines that the applicant will comply with standards established by the Secretary (after consultation with the Attorney General) respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

**(2)(A)** Subject to subparagraphs (D) and (J), the requirements of paragraph (1) are waived in the case of the dispensing (including the prescribing), by a practitioner, of narcotic drugs in schedule III, IV, or V or combinations of such drugs if the practitioner meets the conditions specified in subparagraph (B) and the narcotic drugs or combinations of such drugs meet the conditions specified in subparagraph (C).

**(B)** For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, the practitioner submit to the Secretary a notification of the intent of

the practitioner to begin dispensing the drugs or combinations for such purpose, and that the notification contain the following certifications by the practitioner:

**(i)** The practitioner is a qualifying practitioner (as defined in subparagraph (G)).

**(ii)** With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to provide directly, by referral, or in such other manner as determined by the Secretary--

**(I)** all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder, including for maintenance, detoxification, overdose reversal, and relapse prevention; and

**(II)** appropriate counseling and other appropriate ancillary services.

**(iii)(I)** The total number of such patients of the practitioner at any one time will not exceed the applicable number. Except as provided in subclause (II), the applicable number is 30.

**(II)** The applicable number is--

**(aa)** 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

**(bb)** 100 if the practitioner holds additional credentialing, as defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations);

**(cc)** 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)); or

**(dd)** 275 if the practitioner meets the requirements specified in sections 8.610 through 8.655 of title 42, Code of Federal Regulations (or successor regulations).

**(III)** The Secretary may by regulation change such applicable number.

**(IV)** The Secretary may exclude from the applicable number patients to whom such drugs or combinations of drugs are directly administered by the qualifying practitioner in the office setting.

**(C)** For purposes of subparagraph (A), the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V or combinations of such drugs are as follows:

**(i)** The drugs or combinations of drugs have, under the Federal Food, Drug, and Cosmetic Act or section 262 of Title 42, been approved for use in maintenance or detoxification treatment.

**(ii)** The drugs or combinations of drugs have not been the subject of an adverse determination. For purposes of this clause, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standards respecting the qualifications of practitioners to provide such treatment, or requires standards respecting the quantities of the drugs that may be provided for unsupervised use.

**(D)(i)** A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

**(I)** The notification under subparagraph (B) is in writing and states the name of the practitioner.

**(II)** The notification identifies the registration issued for the practitioner pursuant to subsection (f).

**(III)** If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

**(ii)** Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

**(iii)** Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

**(E)(i)** If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

**(ii)(I)** Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence

to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

**(II)** For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

**(F)(i)** With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

**(ii)** This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

**(G)** For purposes of this paragraph:

**(i)** The term "group practice" has the meaning given such term in section 1395nn(h)(4) of Title 42.

**(ii)** The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

**(I)** The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

**(II)** The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

**(III)** The physician holds a board certification in addiction medicine from the American Osteopathic Association.

**(IV)** The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include--

**(aa)** opioid maintenance and detoxification;

**(bb)** appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;

**(cc)** initial and periodic patient assessments (including substance use monitoring);

**(dd)** individualized treatment planning, overdose reversal, and relapse prevention;

**(ee)** counseling and recovery support services;

**(ff)** staffing roles and considerations;

**(gg)** diversion control; and

**(hh)** other best practices, as identified by the Secretary.

**(V)** The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

**(VI)** The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

**(VII)** The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

**(VIII)** The physician graduated in good standing from an accredited school of allopathic medicine or osteopathic medicine in the United States during the 5-year period immediately preceding the date on which the physician submits to the Secretary a written notification under subparagraph (B) and successfully completed a comprehensive allopathic or osteopathic medicine curriculum or accredited medical residency that--

**(aa)** included not less than 8 hours of training on treating and managing opioid-dependent patients; and

**(bb)** included, at a minimum--

**(AA)** the training described in items (aa) through (gg) of subclause (IV); and

**(BB)** training with respect to any other best practice the Secretary determines should be included in the curriculum, which may include training on pain management, including assessment and appropriate use of opioid and non-opioid alternatives.

**(iii)** The term "qualifying practitioner" means--

**(I)** a qualifying physician, as defined in clause (ii);

**(II)** a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or

**(III)** for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.

**(iv)** The term "qualifying other practitioner" means a nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant who satisfies each of the following:

**(I)** The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.

**(II)** The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant has--

**(aa)** completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

**(bb)** has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant to treat and manage opiate-dependent patients.

**(III)** The nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant is

required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

**(H)(i)** In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

**(I)** Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

**(II)** Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

**(III)** Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

**(ii)** Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

**(I)** Notwithstanding section 903 of this title, nothing in this paragraph shall be construed to preempt any State law that--

**(i)** permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

**(ii)** requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

**(J)** Repealed. Pub.L. 114-198, Title III, § 303(b), July 22, 2016, 130 Stat. 723

**(h) Applicants for distribution of list I chemicals**

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 802(39)(A) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider--

**(1)** maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

**(2)** compliance by the applicant with applicable Federal, State, and local law;

**(3)** any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

**(4)** any past experience of the applicant in the manufacture and distribution of chemicals; and

**(5)** such other factors as are relevant to and consistent with the public health and safety.

**(i) Registration to manufacture certain controlled substances for use only in a clinical trial**

**(1)** For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, not later than 180 days after the date on which the application is accepted for filing.

**(2)** For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

**(j) Emergency medical services that administer controlled substances**

**(1) Registration**

For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General--

**(A)** shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

**(B)** may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (f).

**(2) Option for single registration**

In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

**(3) Hospital-based agency**

If a hospital-based emergency medical services agency is registered under subsection (f), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

**(4) Administration outside physical presence of medical director or authorizing medical professional**

Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is--

**(A)** authorized by the law of the State in which it occurs; and

**(B)** pursuant to--

**(i)** a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

**(ii)** a verbal order that is--

**(I)** issued in accordance with a policy of the agency; and

**(II)** provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient--

**(aa)** in the case of a mass casualty incident; or

**(bb)** to ensure the proper care and treatment of a specific patient.

**(5) Delivery**

A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency--

**(A)** designates the unregistered location for such delivery; and

**(B)** notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

**(6) Storage**

A registered emergency medical services agency may store controlled substances--

**(A)** at a registered location of the agency;

**(B)** at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

**(C)** in an emergency medical services vehicle used by the agency that is--

**(i)** traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

**(ii)** otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

**(7) No treatment as distribution**

The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 828 of this title.

**(8) Restocking of emergency medical services vehicles at a hospital**

Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 828 of this title, provided all of the following conditions are satisfied:

**(A)** The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

**(B)** The hospital maintains a record of such delivery to the agency in accordance with section 827 of this title.

**(C)** If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

**(9) Maintenance of records**

**(A) In general**

A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 827 of this title of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 827(c)(1)(B) of this title.

**(B) Requirements**

Such records--

**(i)** shall include records of deliveries of controlled substances between all locations of the agency; and

**(ii)** shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

**(10) Other requirements**

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that--

**(A)** all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

**(B)** the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

**(C)** the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

**(D)** the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

**(11) Regulations**

The Attorney General may issue regulations--

**(A)** specifying, with regard to delivery of controlled substances under paragraph (5)--

**(i)** the types of locations that may be designated under such paragraph; and

**(ii)** the manner in which a notification under paragraph (5)(B) must be made;

**(B)** specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

**(C)** addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of--

**(i)** shortages of such substances;

**(ii)** a public health emergency; or

**(iii)** a mass casualty event.

**(12) Rule of construction**

Nothing in this subsection shall be construed--

**(A)** to limit the authority vested in the Attorney General by other provisions of this subchapter to take measures to prevent diversion of controlled substances; or

**(B)** to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

**(13) Definitions**

In this section:

**(A)** The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)--

**(i)** who is registered under this chapter;

**(ii)** who is acting within the scope of the registration; and

**(iii)** whose scope of practice under a State license or certification includes the ability to provide verbal orders.

**(B)** The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

**(C)** The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

**(D)** The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that--

**(i)** is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

**(ii)** provides emergency medical services by ground, air, or otherwise; and

**(iii)** is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

**(E)** The term "emergency medical services professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

**(F)** The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

**(G)** The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

**(H)** The term "medical director" means a physician who is registered under subsection (f) and provides medical oversight for an emergency medical services agency.

**(I)** The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

**(J)** The term "registered emergency medical services agency" means--

**(i)** an emergency medical services agency that is registered pursuant to this subsection; or

**(ii)** a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (f).

**(K)** The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (f), which shall be where the agency receives controlled substances from distributors.

**(L)** The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

**(M)** The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

**(N)** The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

**(k) "Factors as may be relevant to and consistent with the public health and safety" defined**

In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 801 of this title.

**CREDIT(S)**

(Pub.L. 91-513, Title II, § 303, Oct. 27, 1970, 84 Stat. 1253; Pub.L. 93-281, § 3, May 14, 1974, 88 Stat. 124; Pub.L. 95-633, Title I, § 109, Nov. 10, 1978, 92 Stat. 3773; Pub.L. 98-473, Title II, § 511, Oct. 12, 1984, 98 Stat. 2073; Pub.L. 103-200, § 3(c), Dec. 17, 1993, 107 Stat. 2336; Pub.L. 106-310, Div. B, Title XXXV, § 3502(a), Oct. 17, 2000, 114 Stat. 1222; Pub.L. 107-273, Div. B, Title II, § 2501, Nov. 2, 2002, 116 Stat. 1803; Pub.L. 109-56, § 1(a), (b), Aug. 2, 2005, 119 Stat. 591; Pub.L. 109-177, Title VII, § 712(a)(3), Mar. 9, 2006, 120 Stat. 263; Pub.L. 109-469, Title XI, § 1102, Dec. 29, 2006, 120 Stat. 3540; Pub.L. 110-425, § 3(b), Oct. 15, 2008, 122 Stat. 4824; Pub.L. 114-89, § 3, Nov. 25, 2015, 129 Stat. 701; Pub.L. 114-145, § 2(a)(1), Apr. 19, 2016, 130 Stat. 354; Pub.L. 114-198, Title III, § 303(a)(1), (b), July 22, 2016, 130

Stat. 720, 723; Pub.L. 115-83, § 2, Nov. 17, 2017, 131 Stat. 1267; Pub.L. 115-271, Title III, §§ 3201(a) to (d), 3202(a), Oct. 24, 2018, 132 Stat. 3943, 3944.)

Notes of Decisions (12)

21 U.S.C.A. § 823, 21 USCA § 823
Current through P.L. 116-19.

End of Document

# Declaration of Suzanne Sisley, M.D.

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

| | | |
|---|---|---|
| In re Scottsdale Research Institute, LLC,<br><br>*Petitioner*. | ) | No. _____ |

**DECLARATION OF SUZANNE SISLEY, M.D.**

1. I am the President and Founder of Scottsdale Research Institute, LLC ("SRI"). I am also the Site Principal Investigator for SRI's FDA-approved clinical trial examining safety/efficacy of whole plant cannabis in combat veterans with treatment-resistant post-traumatic stress disorder ("PTSD"). I make this declaration based on my personal knowledge and in support of the Petition for a Writ of Mandamus.

2. SRI is an Arizona based limited liability company and clinical trials site dedicated to advancing the state of medical care through rigorous research. It is located at 5436 E Tapekim Rd., Cave Creek, AZ 85331 and our website is at http://www.sriresearch.org/. SRI strives to conduct high quality, controlled scientific studies to ascertain the general medical safety

and efficacy of cannabis products and examine forms of cannabis administration. SRI does not encourage recreational use of cannabis.

3. I am also a physician licensed to practice medicine in the State of Arizona and am in good standing. I completed my medical degree at the University of Arizona College of Medicine and did my residency at Good Samaritan Regional Medical Center in the fields of Internal Medicine and Psychiatry. I also served as Clinical Faculty at St. Joseph's Hospital and Medical Center at the MercyCare Adult Medicine Clinic for indigent patients.

4. I have received many honors and awards for my work, both in private practice and in research. For example, in 2001, I won the UA's Leo B. Hart Humanitarian Award from the University of Arizona College of Medicine. I also received the Arizona Medical Association's highest honor, the President's Distinguished Service Award.

5. I have received significant support from patient rights organizations including veteran groups around the country, such as the American Legion. In September 2016, the American Legion passed a resolution in support of our research, urging the DEA to license privately-

funded cannabis production to enable safe and efficient cannabis drug development.[1]

**Private Practice**

6. My primary care practice has always had a focus on treating veterans as well as underserved populations across Arizona.

7. More than a decade ago, I began noticing intractable PTSD and a suicide epidemic among veterans first-hand. PTSD is a mental health condition experienced by some who go through traumatic events. Symptoms vary from individual to individual. Common symptoms include anxiety, insomnia, depression, and nightmares. Currently there are limited approved pharmaceutical remedies for PTSD. Only two anti-depressants, sertraline (Zoloft) and paroxetine (Paxil), are approved by the FDA to treat PTSD.[2]

8. PTSD is quite prevalent among combat veteran populations. The association between combat exposure and PTSD is established. Measured rates of PTSD among combat veterans consistently exceeds 10%.[3] For example, according to a RAND study published on the VA website, the

---

[1] See https://archive.legion.org/bitstream/handle/20.500.12203/5763/2016N011.pdf. See also B. Bender, American Legion to Trump: Allow marijuana research for vets, Politico (May 20, 2017).

[2] See https://www.youtube.com/watch?v=Idujb84MwPE ("Weed 3") at 3:30 (April 19, 2015).

[3] See Hines, L. A., Sundin, J., Rona, R. J., Wessely, S., & Fear, N. T. (2014). Posttraumatic stress disorder post Iraq and Afghanistan: prevalence among military subgroups. Canadian journal of psychiatry. Revue canadienne de psychiatrie, 59(9), 468–479. doi:10.1177/070674371405900903

prevalence of PTSD in Operation Enduring Freedom and Operation Iraqi Freedom was 13.8% out of 1,938 participants. Another study found that prevalence rates for PTSD or depression with serious functional impairment ranged between 8.5% and 14.0%.[4] PTSD is one of the most common psychiatric diagnosis among veterans using the VA hospitals.[5]

9. Suicide rates are also quite high among veteran population. The VA estimates that around 20 veterans per day take their own lives.[6]

10. Many of my veteran clients with PTSD did not respond to conventional medications. Some clients told me that using cannabis helped alleviate their symptoms.[7] For many, cannabis was the only drug that worked, reversing insomnia or easing depression and anxiety. Patients told me that cannabis effectively quelled nightmares, flashbacks, and hypervigilance.

11. This first-hand experience inspired me to conduct clinical trials on the safety and efficacy of cannabis use to suppress treatment resistant

---

[4] See https://www.ptsd.va.gov/professional/treat/essentials/epidemiology.asp.

[5] Ralevski, E., Olivera-Figueroa, L. A., & Petrakis, I. (2014). PTSD and comorbid AUD: a review of pharmacological and alternative treatment options. Substance abuse and rehabilitation, 5, 25–36. doi:10.2147/SAR.S37399.

[6] See https://www.mentalhealth.va.gov/docs/2016suicidedatareport.pdf at 22.

[7] See Weed 3 at 5:00.

PTSD, which I discussed in CNN's "Weed 3: The Marijuana Revolution,"[8] an April 19, 2015 special report by CNN's chief medical correspondent Dr. Sanjay Gupta. This documentary not only explains in detail how veterans that struggle with PTSD have come to rely on cannabis, but also how we overcame numerous obstacles to be able to do our research, which I discuss below.

## The Road to Clinical Trials

12. I struggled for seven years to get approval from four different federal agencies to conduct clinical trials of cannabis as a treatment for PTSD symptoms in veterans.

13. In 2009, I began collaborating with the Multidisciplinary Association for Psychedelic Studies (MAPS) on a proposal for the FDA. On Nov. 11, 2010, MAPS' clinical research team submitted our protocol to the FDA, and FDA approval came in April 2011.

14. On July 30, 2012, we submitted the protocol to the University of Arizona Institutional Review Board (IRB), which approved the study in October 2012.

[8] Although the video does not appear to be available from CNN, the video is widely available online, for example on YouTube at https://www.youtube.com/watch?v=Idujb84MwPE. I am introduced in the video at 3:30, and our struggle to obtain all the necessary government permissions begins at 5:30.

15. Shortly after FDA approval, we sent the proposal to NIDA and PHS for approval. After a series of rejections, we finally obtained approval from these agencies around March 2014. That approval was critical because it allowed us to be able to purchase federally legal cannabis from NIDA, the only source of cannabis legal for use in federally regulated research.

16. On April 17, 2014, NIDA informed us that it did not have the cannabis we needed for our study. Shortly after that, NIDA told us that it would have to grow the cannabis we needed for our protocol.

17. In June 2014, I was released by the University of Arizona. They chose not to renew my contract of employment and two other subcontracts. My assistant professorship was terminated. As a result, I lost my healthcare, primary income, and pension. And without an academic appointment, I was unable to continue my research with the university. I discussed this in an interview with CNN's Sanjay Gupta in July 2014.[9]

18. On November 2, 2015, we submitted our protocol to the DEA. As part of the approval process, the DEA inspected SRI. In April 2016, the DEA approved my Schedule I license to do research with cannabis, which is still active. That license removed the last barrier to the study.

[9] The interview is available at https://www.cnn.com/2014/07/12/health/marijuana-researcher-arizona/index.html.

19. Our phase II clinical trials titled "Placebo-Controlled, Triple-Blind, Randomized Crossover Pilot Study of the Safety and Efficacy of Four Different Potencies of Smoked Marijuana in 76 Veterans with Chronic, Treatment-Resistant Posttraumatic Stress Disorder (PTSD)" began in early 2017, and we concluded it in early 2019. SRI treated 76 participants as part of the study. MAPS sponsored the study and it was funded with a $2.1 million grant from the Colorado Department of Public Health and Environment. The study's protocol is available online.[10] We are aiming to publish our results in late 2019. The data looks promising, and justifies further examination with an alternative supply of high-quality natural cannabis flower.

**NIDA Cannabis**

20. On August 10, 2016, NIDA approved SRI's request to order 6.3kg of cannabis for our clinical trials. We had requested multiple cannabis strains with varying levels of THC and CBD, including high THC, high CBD, balanced THC/CBD, and placebo. On August 25, 2016, I received the first shipment. The cannabis arrived frozen, in dried bulk form. SRI tested the cannabis at a DEA-licensed laboratory.

21. Generally speaking, the NIDA cannabis SRI received looked nothing like commercial grade medical cannabis one can buy from

[10] See https://www.sriresearch.org/MJP1-A6V1-FINAL-16MAR2017-Web%20(1).html.

dispensaries states where medicinal cannabis is legal. NIDA cannabis consistently appears to have extraneous material like sticks, stems, and seeds. Many packages looked like the green powder shown below from a 2017 article on pbs.org that I am quoted in:[11]

22. I am also quoted in a 2017 Washington Post article titled "Government marijuana looks nothing like the real stuff. See for yourself," where a side by side comparison of commercial medicinal cannabis and NIDA cannabis can be seen:[12]

[11] See C. Hellerman "Scientists say the government's only pot farm has moldy samples — and no federal testing standards," PBS (Mar. 8, 2017) (https://www.pbs.org/newshour/nation/scientists-say-governments-pot-farm-moldy-samples-no-guidelines). I took this picture.

[12] See C. Ingraham and T. Chappell, "Government marijuana looks nothing like the real stuff. See for yourself," Washington Post (Mar. 13, 2017) (https://www.washingtonpost.com/news/wonk/wp/2017/03/13/government-marijuana-looks-nothing-like-the-real-stuff-see-for-yourself/?utm_term=.2dcae33401d3/).


23. In my opinion, both as a researcher and physician, the quality of this cannabis had an adverse impact on the study results and sometimes on the study subjects. For example, I noticed that bronchial irritation was a common complaint among the study subjects. I believe this side effect could have been mitigated if not eliminated had SRI been able to grow and use its own cannabis (which would have only contained the flowering tops of the plant without the extraneous plant material that can burn more harshly and cause excessive mucosal irritation) or simply if SRI could have used other cannabis that did not have extraneous material and excessively high levels of mold.

24. Before I could use the study drug, I had to sign a Release and Indemnity Agreement and take full responsibility for the preparation and

distribution of the government's cannabis. Physicians and principal investigators should not be put into a position where we must knowingly distribute cannabis flower to enrolled study subjects, while then being forced to accept full liability for this suboptimal study drug.

25. NIDA cannabis was not only inadequate for the Phase II trial we just completed, but will be inadequate for further studies, such as Phase III clinical trials or other Phase II clinical trials. The presence of sticks, stems, and seeds and significant mold makes this drug unsuitable for clinical research in certain patient populations.

26. Because NIDA cannabis is inadequate, SRI is now looking to import cannabis from a Canadian company for other projects, such as clinical trials to test the safety and efficacy of cannabis versus fentanyl for management of breakthrough pain in terminal cancer patients.

**Application to DEA**

27. On October 1, 2016, I submitted SRI's application for registration under the Controlled Substances Act. I submitted answers to supplemental questionnaire to DEA shortly after.

28. In the supplemental questionnaire, I told DEA that SRI was conducting an FDA approved Phase 2 randomized controlled trial evaluating the safety and efficacy of cannabis for military veterans with PTSD, that SRI

planned to move into Phase 3 trials in next 3 years, and that it would need a supply of cannabis other than from NIDA. The purpose of SRI's application was to allow it to cultivate cannabis that could be used for Phase 3 FDA trials. The only way cannabis could ever be approved as an FDA prescription medicine is through Phase 3 trials.

29. I explained that once SRI was licensed, it would supply its own internal, FDA sanctioned and licensed clinical trials. I also discussed supplying academic and private researchers across the country to provide them with a consistent supply of medical product for clinical trials. I did not list anybody else as prospective customers because I am unaware of any other researchers allowed to do clinical trials involving cannabis.

30. Since I filed SRI's application more than two-and-a-half years ago, I have followed up with the DEA numerous times. I believe I called DEA five times between June 2017 to August 2018. I also exchanged e-mails with the agency on June 22, 2017, but after a follow up e-mail on July 15, 2017, I did not hear back from the agency.

31. One year later, I followed up on my application again in an August 30, 2018 e-mail, writing:

> I have contacted my local DEA office regularly asking them the status of our application over the past two years and continue to get a vague response saying they have no idea when the application will ever be processed.

> Can you provide us another update from the national office on when the applications will be evaluated?
>
> I know we've discussed this on the phone several times over the last few years and I continue to hear from you that you are unsure of when this application above will be assessed. So given the continual uncertainty from your office, I've stopped inquiring with national office because this seemed futile.

In response, I was only told that the status of SRI's application remained the same.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on _5_, June 2019.

Suzanne Sisley, M.D.
President of Petitioner SRI, LLC